REMARKS

Election/Restrictions

Claims 4, 32-34, 47-49, 51-56, 65, 66, 77 and 78 have been withdrawn from consideration as being drawn to a non-elected invention and species of the invention. The Applicant has chosen to maintain these claims in the subject application for possible reinstatement following allowance of one or more independent base claims. Additionally, withdrawn claim 47 has been amended to correct an informality.

Claim Rejections – 35 USC §102 and §103

Claims 2, 3, 15, 28-31, 35, 37, 38, 42-46 and 50 have been rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,281,262 to Shikinami. Claims 36, 57, 58 and 80-88 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Shikinami, and claims 39-41, 59-64, 67-76 and 79 have been rejected as being unpatentable over Shikinami in view of U.S. Patent No. 6,491,724 to Ferree.

The Applicant note that "an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co. Ltd., 868 F.2d 1226, 1236, 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989). Additionally, the Office Action asserts that "[w]ith regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Shikinami". (Pages 3-4 of the Office Action). As set forth below, independent claims 28 and 42 have been amended to recite structural features that are submitted to clearly distinguish over Shikinami.

Independent Claim 28 and Dependent Claims 2, 3, 15, 29-31, 35-41, 46, 50, 57, 58 and 80-88

Independent claim 28 has been rejected as being anticipated by Shikinami. In response to this rejection, independent claim 28 has been amended and now recites, in pertinent part, a body composed of a shape memory polymeric material and comprising a peripheral sidewall "defining an interior cavity and vertebral bearing surfaces at opposite ends of the peripheral sidewall

defining openings in communication with the interior cavity", "wherein the peripheral sidewall in the first configuration has a first lateral dimension and the vertebral bearing surfaces each define a first bearing surface area", and "wherein the peripheral sidewall in the second configuration has a second lateral dimension greater than the first lateral dimension and the vertebral bearing surfaces each define a second bearing surface area significantly greater than the first bearing surface area". The amendments to independent claim 28 are supported, for example, in paragraphs [0027], [0028], [0030] and [0031] and in Figures 1-5 of the published application.

The Applicant notes subject matter added to independent claim 28 was present in independent claims 42 and 59 and dependent claim 37, and that each of these claims has already been subjected to examination. Accordingly, the amendments incorporated into independent claim 28 are submitted to not raise new issues that would require further consideration and/or additional searching. Additionally, the Applicant notes that dependent claim 37 has been cancelled from the subject application without prejudice for possible submission in a continuing application, and that claims 38 and 39 have been amended to depend from independent claim 28 in view of the cancellation of dependent claim 37.

As an initial matter, the device illustrated in Figures 24 and 25 of Shikinami does not comprise an expandable spacer for implantation between opposing endplates of adjacent vertebrae, and the device likewise does not include a peripheral sidewall defining vertebral bearing surfaces at opposite ends thereof, as recited in independent claim 28. To the contrary, the device illustrated in Figures 24 and 25 comprises a vascular cylindrical-shaped stent initially positioned within a blood vessel 110 while in an original shape 12, and which is transitioned from the original shape 12 to the expanded shape 12a within the blood vessel 110 to prevent vascular reconstruction. While the stent includes a peripheral sidewall, the sidewall does not define vertebral bearing surfaces at opposite ends thereof.

Additionally, although the expanded shape 12a of the stent arguably has a second lateral dimension that is greater than a first lateral dimension defined by the original shape 12 of the stent, the expanded shape 12a does not have vertebral bearing surfaces at opposite ends thereof which define a second bearing surface area significantly greater than a first bearing surface area

defined by the original shape 12 of the stent. As clearly shown in Figures 24 and 25, while the shape or outer profile of the sidewall is modified between the original shape 12 and the expanded shape 12a, the thickness and cross-sectional area of the sidewall remain unchanged. As a result, the surface area defined by the ends of the stent sidewall when expanded from the original shape 12 to the expanded shape 12a remains unchanged. Accordingly, the surface area defined by the ends of the stent sidewall when in the expanded shape 12a is not significantly greater than the surface area defined by the ends of the stent sidewall when in the original shape 12. To the contrary, the surface area defined by the ends of the stent sidewall remains unchanged as the stent sidewall is transitioned from the original shape 12 to the expanded shape 12a. In other words, although the overall shape or outer profile of the stent sidewall changes between the original and expanded shapes 12, 12a, such change in shape/outer profile does not result in a greater surface area defined by the ends of the stent sidewall.

Additionally, Figures 1 and 2 of Shikinami disclose a device that is used for vascular anastomosis (i.e., to interconnect adjacent blood vessels 102). While the vascular device includes a peripheral sidewall, the sidewall does not define vertebral bearing surfaces at opposite ends thereof. Additionally, although the vascular device is configured to change shape, the vascular device contracts about the blood vessel sections 102 upon absorption of thermal energy to transition the vascular device between the original configuration 1 and the contracted configuration 1a. Accordingly, the vascular device is not provided "in a first configuration sized to overlay a first portion of a vertebral endplate wherein said body upon absorption of thermal energy expands to a second configuration sized to overlay a second portion of the vertebral endplate . . . having a greater area than the first portion", as recited in independent claim 28. To the contrary, the vascular device contracts to the contracted configuration 1a from the original configuration 1 upon absorption of thermal energy, which is directly contrary to the spacer body recited in independent claim 28. Moreover, the sidewall of the device has a first lateral dimension when in the original configuration 1 and a second lateral dimension in the contracted configuration that is less than the first lateral dimension, which once again is directly contrary to the spacer body recited in independent claim 28 which recites that the expanded configuration of

the spacer body is sized to overlay a second portion of a vertebral endplate "having a greater area than the first portion".

Furthermore, Figures 3-8 of Shikinami disclose other types of vascular anastomosis devices which likewise contract from an original configuration to a smaller contracted configuration upon absorption of thermal energy, and which similarly have a first lateral dimension when in the original configuration and a second lateral dimension in the contracted configuration that is less than the first lateral dimension. Additionally, Figures 9-13 of Shikinami likewise disclose various types of device which contract from an original configuration to a smaller contracted configuration upon absorption of thermal energy, and which similarly have a first lateral dimension when in the original configuration and a second lateral dimension in the contracted configuration that is less than the first lateral dimension. Figures 14-19 of Shikinami disclose device that each have a solid cross section, and therefore do not define "an interior cavity and vertebral bearing surfaces at opposite ends of the peripheral sidewall defining openings in communication with the interior cavity", as recited in independent claim 28.

Figures 20-23 of Shikinami disclose devices which operate in a manner similar to the expandable stent illustrated in Figures 24 and 25. Specifically, the expandable devices illustrated in Figures 20-23 are configured to expand between an original shape 10, 11 and an expanded shape 10c, 11c. Although the expanded shape 10c, 11c arguably has a second lateral dimension greater than a first lateral dimension defined by the original shape 10, 11, the expanded shape 10c, 11c does not have vertebral bearing surfaces at opposite ends which define a second bearing surface area significantly greater than a first bearing surface area defined by the original shape 10, 11. While the sidewall of the device changes shape between the original shape 10, 11 and the expanded shape 10c, 11c, the thickness and cross-sectional area of the sidewall remain unchanged, and the surface area defined by opposite ends of the device likewise does not change. Accordingly, the surface area defined by the ends of the device when expanded to the expanded shape 10c, 11c is not significantly greater than the surface area defined by the ends of the device when in the original shape 10, 11, as recited in independent claim 28. Finally, as illustrated in Figures 26-28, shown therein is a device which contracts from an original configuration 13 to a

smaller contracted configuration 13a upon absorption of thermal energy, and which has a first lateral dimension when in the original configuration 13 and a second lateral dimension in the contracted configuration 13a that is less than the lateral dimension defined by the original configuration 13. Once again, this device is configured differently compared to the expandable spacer recited in independent claim 28.

Since Shikinami fails to disclose or suggest each of the elements and features recited in independent claim 28, the Applicant submits that independent claim 28 is not anticipated by Shikinami, and withdrawal of the rejection of independent claim 28 is respectfully requested. Claims 2, 3, 15, 29-31, 35, 36, 38-41, 46, 50, 57 and 58 depend either directly or indirectly from independent claim 28, and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 28. Accordingly, the Applicant request allowance of independent claim 28 and the claims depending therefrom.

Independent Claim 42 and Dependent Claims 43 and 44

Independent claim 42 has been rejected as being anticipated by Shikinami. In response to this rejection, independent claim 42 has been amended and now recites, in pertinent part, a body composed of a shape memory polymeric material and comprising a peripheral sidewall "defining an interior cavity and vertebral bearing surfaces at opposite ends of the peripheral sidewall defining openings in communication with the interior cavity", "wherein the peripheral sidewall in the first configuration has a first lateral dimension and a first sidewall thickness defining a first cross-sectional area", and "wherein the peripheral sidewall in the second configuration has a second lateral dimension greater than the first lateral dimension and a second sidewall thickness greater than the first sidewall thickness, the second sidewall thickness defining a second cross-sectional area significantly greater than the first cross-sectional area". The amendments to independent claim 42 are supported, for example, in paragraphs [0027], [0028], [0030] and [0031] and in Figures 1-5 of the published application. The Applicant notes that the subject matter recited in independent claim 42 is similar to that recited in independent claim 28 which, as discussed above, is submitted to be patentable over Shikinami.

As an initial matter, the device illustrated in Figures 24 and 25 of Shikinami does not

comprise an expandable spacer for implantation between opposing endplates of adjacent vertebrae, and the device likewise does not include a peripheral sidewall defining an interior cavity and vertebral bearing surfaces at opposite ends of the peripheral sidewall, as recited in independent claim 42. Additionally, although the expanded shape 12a of the stent illustrated in Figures 24 and 25 arguably has a second lateral dimension that is greater than a first lateral dimension defined by the original shape 12 of the stent, the expanded shape 12a does not have a peripheral sidewall having a sidewall thickness defining a cross-sectional area which is significantly greater than a sidewall thickness and cross-sectional area defined by the original shape 12 of the stent. Indeed, as shown in Figures 24 and 25, while the sidewall of the stent changes shape between original shape 12 and the expanded shape 12a, the thickness and cross-sectional area of the stent sidewall remain unchanged. In other words, although the overall shape or outer profile of the stent sidewall changes between the original and expanded shapes 12, 12a, such change in shape/outer profile does not result in a greater thickness of the stent sidewall or a greater cross-sectional area defined by the thickness of the stent sidewall.

Additionally, as discussed above, Figures 1-8 of Shikinami illustrate devices that are used for vascular anastomosis (i.e., to interconnect adjacent blood vessels 102). While these vascular devices each include a peripheral sidewall, the sidewall does not define vertebral bearing surfaces at opposite ends thereof. Additionally, although the vascular devices change shape upon absorption of thermal energy, the vascular devices are configured to contract about the blood vessels 102 upon absorption of thermal energy between the original configurations and the contracted configurations. Accordingly, the vascular devices are not provided "in a first configuration sized to overlay a first portion of a vertebral endplate wherein said body upon absorption of thermal energy expands to a second configuration sized to overlay a second portion of the vertebral endplate . . . having a greater area than the first portion", as recited in independent claim 42. To the contrary, the vascular devices contract from the original configuration to a smaller contracted configuration upon absorption of thermal energy, which is directly contrary to the spacer body recited in independent claim 42. Moreover, the sidewall of the vascular devices has a first lateral dimension when in the original configuration and a second

lateral dimension in the contracted configuration that is less than the first lateral dimension, which once again is directly contrary to the spacer body recited in independent claim 42.

Additionally, Figures 9-13 of Shikinami likewise disclose various types of device which contract from an original configuration to a smaller contracted configuration upon absorption of thermal energy, and which similarly have a first lateral dimension when in the original configuration and a second lateral dimension in the contracted configuration that is less than the first lateral dimension. Figures 14-19 of Shikinami disclose device that each have a solid cross section, and therefore do not define "an interior cavity and vertebral bearing surfaces at opposite ends of the peripheral sidewall defining openings in communication with the interior cavity", as recited in independent claim 42.

Figures 20-23 of Shikinami disclose devices which operate in a manner similar to the expandable stent illustrated in Figures 24 and 25. Specifically, the expandable devices illustrated in Figures 20-23 are configured to expand between an original shape 10, 11 and an expanded shape 10c, 11c. Although the expanded shape 10c, 11c arguably has a second lateral dimension greater than a first lateral dimension defined by the original shape 10, 11, the expanded shape 10c, 11c does not have a peripheral sidewall having a sidewall thickness defining a cross-sectional area which is significantly greater than a sidewall thickness and cross-sectional area defined by the original shape 10, 11. Indeed, while the sidewall changes shape between original shape 10, 11 and the expanded shape 10c, 11c, the thickness and cross-sectional area of the sidewall remain unchanged as the sidewall is transitioned from the original shape 10, 11 to the expanded shape 10c, 11c. In other words, although the overall shape or outer profile of the sidewall changes between the original and expanded shapes, such change in shape/outer profile does not result in a greater thickness of the sidewall or a greater cross-sectional area defined by the thickness of the sidewall. Finally, Figures 26-28 illustrate a device which contracts from an original configuration 13 to a smaller contracted configuration 13a upon absorption of thermal energy, and which has a first lateral dimension when in the original configuration 13 and a second lateral dimension in the contracted configuration 13a that is less than the lateral dimension defined by the original configuration 13. Once again, this device is configured differently compared to the expandable spacer recited in independent claim 42.

Since Shikinami fails to disclose or suggest each of the elements and features recited in independent claim 42, the Applicant submits that independent claim 42 is not anticipated by Shikinami, and withdrawal of the rejection of independent claim 42 is respectfully requested. Claims 43 and 44 depend either directly or indirectly from independent claim 42 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 42. Accordingly, the Applicant request allowance of independent claim 42 and claims 43 and 44 depending therefrom.

Independent Claim 45

Independent claim 45 has been cancelled without prejudice for possible submission and consideration in a continuing application.

Independent Claim 59 and Dependent Claims 60-64, 67-76 and 79

Independent claim 59 has been rejected as being unpatentable over the Shikinami reference in view of the Ferree reference. The Applicant has amended independent claim 59 to depend from independent claim 42. Additionally, dependent claims 62 and 73-76 have been cancelled without prejudice for possible submission in a continuing application. The Applicant submits that dependent claim 59 and claims 60, 61, 63, 64, 67-72 and 79 depending therefrom are patentable for at least the reasons set forth above in support of the patentability of independent base claim 42. Accordingly, withdrawal of the rejection of dependent claims 59-61, 63, 64, 67-72 and 79 and allowance of the same are respectfully requested.

CONCLUSION

In view of the foregoing remarks and amendments, it is respectfully submitted that the Applicant's application is in condition for allowance with pending claims 2-4, 15, 28-36, 38-44, 46-61, 63-72 and 77-88.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By: _____

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